

REMARKS

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

Amendments have been proposed for claims 14, 16, 19 and 22, support for which can be found in original claims 15 and 24, which are herein cancelled. Thus, after amending the claims as set forth above, claims 14, 16-23, and 25-26 will be pending in this application.

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. Rejections under 35 U.S.C. §103(a)

The examiner rejects claims 14-26 under 35 U.S.C. §103(a) as allegedly being unpatentable over Sato *et al.* and/or Kishimoto *et al.* in view of Gross *et al.* and Farkas *et al.* Applicants respectfully traverse the rejection.

The examiner is of the view that "[t]here is no question that the person of ordinary skill in the art would expect at least a reduction in symptoms due to the inhibition of IL-6 antibody, as evidenced by the primary references." Applicants respectfully disagree. In this regard, applicants believe the examiner mischaracterizes the state of the art at the priority date of the present application.

As previously noted, at the time of the priority date of the present application, it was known that not only IL-6 but also other cytokines relate to acute pancreatitis, and that once the cytokine network involving IL-6 and other cytokines is activated, blocking of a cytokine is compensated by other cytokines. Therefore, one of ordinary skill in the art at the time of the priority date of the present application would have understood that blocking a single cytokine is not effective to treat or alleviate a disease or a symptom involving said cytokine, because the blocking of the cytokine is compensated by other cytokines.

Contrary to the expectations of the field, applicants unexpectedly discovered that blocking IL-6 signal transduction in fact alleviates acute pancreatitis. For example, see Fig. 5. Therefore, the cited art does not presage the claimed invention.

In addition, the examiner criticizes the Examples, stating that a result of a pharmacological test was obtained by injecting or administering an anti-IL-6 receptor antibody prior to induction of acute pancreatitis. While the injection or administration was carried out prior to induction of the acute pancreatitis, the invention is not characterized by the timing of the administration of the anti-IL-6 receptor antibody. Rather, the invention is characterized by the fact that the usefulness of the anti-IL-6 receptor antibody for treatment of the acute pancreatitis has been elucidated, for the first time, and experimentally confirmed. In addition, it should be noted that in experiments using animal models, such as a transgenic mouse, administration of a test substance prior to artificial induction of a target disease is a standard technique accepted in the art.

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date February 16, 2007

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